UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| SECURITIES AND EXCHANGE COMMISSION, | : | |
| Plaintiff, | : | Civil Action No. 05-11805-NMG |
| v. | : | |
| RICHARD F. SELDEN, | : | |
| Defendant. | : | |
| RICHARD F. SELDEN, | : | |
| Plaintiff, | : | Civil Action No. 06-11807-NMG |
| v. | : | |
| UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration, | : | |
| Defendants. | : | |

**RICHARD F. SELDEN'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW ON HIS CROSS-MOTION TO PRECLUDE ADMISSION OF FDA EVIDENCE**

Defendant-plaintiff Richard F. Selden ("Dr. Selden"), by his undersigned counsel, respectfully submits the following proposed findings of fact and conclusions of law in support of his Cross-Motion To Preclude Admission Of FDA Evidence.

## FINDINGS OF FACT

1. On October 22, 2002, approximately three weeks after the Securities and Exchange Commission ("SEC") commenced its investigation of Dr.

Selden, the SEC sent a request for materials to the United States Food and Drug Administration[1] in the form of an access letter. Ex. A.[2]

2. Within four weeks, on November 18, the FDA provided the first of several subsequent productions of documents to the SEC. Also around this time, the SEC began conducting informal, "off the record" interviews of potential FDA witnesses.

3. On January 23, 2003, the FDA produced additional documents to the SEC.

4. On February 10, 2003, the SEC sent a second request for documents from the FDA. Ex. B.

5. On May 15, 2003, the SEC sent copies of press releases to the FDA relating to the SEC's investigation of TKT. Ex. C.

6. On May 28, 2003, the FDA produced additional documents to the SEC. Ex. D.

7. On May 30, 2003, with the knowledge of the FDA General Counsel's Office, the SEC conducted an informal, "off the record" interview of Dr. Mark Walton, one of the key FDA reviewers of TKT's biologics license application for Replagal. Ex. E.

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[1] For purposes of this submission, "FDA" shall refer collectively to defendants the United States Food and Drug Administration and Andrew C. von Eschenbach, in his official capacity as acting commissioner of the FDA.

[2] References to "Ex. __" are to the exhibits attached to the October 5, 2006 Affidavit Of Justin J. Daniels In Support Of Plaintiff's Motion For Order To Show Cause And Preliminary Injunction, submitted in Selden v. FDA, et al., Civ. No. 06-11807-NMG (D. Mass.) (Docket No. 4). They are not re-attached here. However, for the Court's reference, an additional set of Dr. Selden's Motion For Preliminary Injunction papers, including the Daniels Affidavit, is being submitted today in S.E.C. v. Selden, Civ. No. 05-11805-NMG (D. Mass.).

8. On June 25, 2003, the SEC sought the formal testimony from Dr. Walton pursuant to 21 C.F.R. § 20.1, et seq. Ex. F.

9. On June 26, 2003, the FDA responded to the SEC's request for Dr. Walton's testimony. The FDA authorized the testimony "[i]n keeping with our policy of assisting other government agencies in matters related to the protection of the public health." Ex. F.

10. On July 22, 2003, Dr. Walton gave sworn testimony to the SEC.

11. On September 1, 2005, the SEC filed a Complaint against Dr. Selden in the United States District Court for the District of Massachusetts. S.E.C. v. Selden, Civ. No. 05-11805-NMG (D. Mass.) ("SEC Action"). Ex. G.

12. On October 28, 2005, in connection with the SEC Action, Dr. Selden issued two federal subpoenas (the "Subpoenas") out of the United States District Court for the District of Columbia ("D.C. Court"). The FDA first refused to accept service of the Subpoenas, then did so several days later. Exs. H & I.

13. On November 9, 2005, the FDA Chief Counsel's Office informed Dr. Selden by letter that it would not comply in any respect with the Subpoenas and requested that they be withdrawn. Among other things, the FDA stated that it was not a "person" and therefore could not be subpoenaed under Fed. R. Civ. P. 45. Ex. J.

14. On November 15, 2005, Dr. Selden responded to the FDA's letter, restating the essential nature of the subpoenaed discovery, reviewing the FDA's extensive prior cooperation with the SEC in this case, reviewing the relevant case law, and requesting that the FDA reconsider its position. Ex. K.

15. On November 17, 2005, this Court held a Rule 16 scheduling conference in this action. At that conference, counsel for Dr. Selden informed the Court of the Subpoenas and the discovery dispute with the FDA, and advised that the open issue of FDA discovery could impact the scheduling of the SEC Action going forward.

16. Six days later, after agreement with the FDA could not be reached, Dr. Selden filed a motion to compel in the D.C. Court. S.E.C. v. Selden, Misc. Case No. 1:05-mc-00476-RMU (D.D.C., filed Nov. 23, 2005). Briefing on the motion took place over the next several weeks.

17. On February 10, 2006, the D.C. Court issued an order holding the matter in abeyance pending decision by the U.S. Court of Appeals for the District of Columbia Circuit in Yousuf v. Samantar, No. 05-5197 (D.C. Cir.) ("Yousuf"), on the grounds that the enforcement of the federal governmental subpoena in Yousuf raised some of the same issues raised during the proceedings before the D.C. Court (which included the issue of whether the federal government and its agencies were "persons" under Rule 45). Ex. L.

18. Days later, Dr. Selden moved the U.S. Court of Appeals for leave to file a brief in Yousuf as an amici curia, arguing that any rule fashioned by the Court should take into account civil actions -- such as the SEC Action -- where the government is the plaintiff and where the subpoenaed federal agency had already provided one-sided cooperation, assistance and support to the plaintiff.

19. The Department of Justice filed a brief opposing Dr. Selden's motion for leave, and the U.S. Court of Appeals denied Dr. Selden's motion.

20. In light of the FDA's refusal to comply with the Subpoenas as well as the continuing proceedings in the D.C. Court, Dr. Selden filed an unopposed motion with this Court seeking to extend all pretrial deadlines by six months. See SEC Action, Docket Nos. 14 & 15.

21. On March 24, 2006, this Court granted Dr. Selden's motion to amend the Scheduling Order and set the following revised deadlines, among others:

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| Sept. 29, 2006: | Last day to serve written discovery |
| Oct. 30, 2006: | Last day to answer written discovery |
| Feb. 28, 2007: | Last day for fact depositions |
| June 30, 2007: | Last day of expert discovery |
| Aug. 17, 2007: | Last day to file dispositive motions |

22. On March 29, 2006, Dr. Selden served "Touhy" requests for testimony on the FDA. Ex. M.

23. During April and May 2006, at the prompting of the SEC, the FDA began a dialogue with Dr. Selden. Numerous phone calls took place. During this time Dr. Selden agreed to narrow several of his requests.

24. On June 16, 2006, the D.C. Circuit issued its ruling in Yousuf v. Samantar, 451 F.3d 248 (D.C. Cir. 2006), holding, among other things, that the federal government is subject to subpoena under Rule 45.

25. On June 30, 2006, pursuant to the D.C. Court's February 10, 2006 Order (see supra ¶ 17), Dr. Selden and the FDA submitted memoranda regarding the impact of the Yousuf decision on the motions before the D.C. Court.

26. On July 10, 2006, more than three months after the FDA received Dr. Selden's March 2006 Touhy requests (see supra ¶ 22), Dr. Selden received a response from the FDA. The FDA stated it was refusing to produce any of the witnesses requested

by Dr. Selden for testimony, but for the witness from whom the SEC had previously taken testimony, Dr. Mark Walton. The FDA's sole stated rationale for denying the testimony was that the testimony would "likely be duplicative." Ex. N.

27. On July 12, 2006, Dr. Selden responded to the FDA's Touhy letter, pointing out the many respects in which the testimony being sought is not duplicative and requesting the FDA to reconsider its refusal to produce the witnesses. Ex. O. Although counsel for Dr. Selden was informed on at least two occasions by FDA counsel that a response to the letter from the FDA would be forthcoming, to date there has been no response from the FDA.

28. During July 2006, with respect to documents, the dialogue between Dr. Selden and the FDA continued; however, despite making progress on the substance, the FDA had yet to produce a single piece of paper.

29. On August 16, 2006, the D.C. Court granted in its entirety Dr. Selden's motion to compel FDA compliance with the Subpoenas and denied the FDA's motion to quash same. The Court also directed the parties to submit a Joint Status Report and to provide a courtesy copy to this Court. Ex. P.

30. Between August 16 and August 25, 2006, counsel for the FDA and Dr. Selden engaged in extensive negotiations concerning the scope of what the FDA would produce in response to the D.C. Order. As a result, several of Dr. Selden's original subpoena requests were narrowed or eliminated altogether.

31. On August 25, 2006, a Joint Status Report was filed with the D.C. Court and a courtesy copy was provided to this Court. See SEC Action, Docket No. 16. Among other things, the FDA stated that the agency needed at least 22 months to review

and produce the agreed-to documents. (According to this estimate, one person working full time needed six-to-seven weeks to review and produce a single box.) Ex. Q.

32. On September 28, 2006, the Court held a status conference in this action, during which the issue of the FDA's 22-month production schedule was discussed. See SEC Action, Docket No. 18.

33. On October 5, 2006, Dr. Selden filed a separate action in this Court for declaratory and injunctive relief against the FDA and Andrew C. von Eschenbach, in his official capacity as acting commissioner of the FDA, pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 701-06, the Mandamus Act, 28 U.S.C. § 1361, the Freedom of Information Act, 5 U.S.C. § 552, and the Federal Declaratory Judgment Act, 28 U.S.C. § 2201. See Richard F. Selden v. FDA, et al., Civ. No. 06-11807-NMG (D. Mass.) (the "FDA Action"), designated as a related case to the SEC Action. The FDA Action seeks declaratory and injunctive relief to require the FDA's meaningful compliance with the D.C. Order. In connection therewith, Dr. Selden simultaneously filed a Motion For Order To Show Cause And Preliminary Injunction and supporting papers. See FDA Action, Docket Nos. 2-5. The sole purpose of the motion is to obtain a timely production by the FDA of documents already ordered to be produced by the D.C. Court and already negotiated and agreed to by the FDA.

34. On October 19, 2006, the SEC moved to intervene in the FDA Action and submitted an opposition to Dr. Selden's motion, styled as a "Statement Of Position Concerning Motion For Preliminary Injunction." See FDA Action, Docket No. 9, Attach. #1. In that Statement, the SEC argues that the way to speed up the FDA's 22-month schedule is to further cut back the discovery Dr. Selden seeks.

35. On October 20, 2006, the FDA submitted its own opposition, arguing that this Court does not have jurisdiction to hear the dispute and that the only appropriate forum for consideration of the issue is the D.C. Court. See FDA's Memorandum Of Law In Opposition To Plaintiff's Motion For Preliminary Injunction (FDA Action, Docket No. 14). The FDA has also moved to dismiss the FDA Action for lack of subject matter jurisdiction. See FDA's Motion and Memorandum Of Law In Support Of Defendants' Motion To Dismiss For Lack Of Jurisdiction (FDA Action, Docket Nos. 12 & 13).

## CONCLUSIONS OF LAW

1. It is a basic principle of the federal judicial system that courts have the inherent power to manage and control the disposition of the cases on their dockets in furtherance of "the enhancement of the court[s'] processes," In re Atl. Pipe Corp., 304 F.3d 135, 143 (1st Cir. 2002), and to ensure the courts' fundamental role as "a guarantor of fairness," Weinberger v. Great N. Nekoosa Corp., 925 F.2d 518, 525 (1st Cir. 1991). As stated by the United States Supreme Court: "These powers are 'governed not by rule or statute but by the control necessarily vested in courts to manage their own affairs so as to achieve the orderly and expeditious disposition of cases.'" Chambers v. NASCO, Inc., 501 U.S. 32, 43 (1991) (citing Link v. Wabash R.R. Co., 370 U.S. 626, 630-31 (1962)).

2. Further, the exercise of the court's power can "take[] many forms." Atl. Pipe, 304 F.3d at 143. As held by the First Circuit Court of Appeals: "This circuit has recommended a straightforward approach to ensure that the spirit of open discovery embodied in Rule 26 is not undermined either by evasion or by dilatory tactics." Thibeault v. Square D Co., 960 F.2d 239, 244 (1st Cir. 1992). Among other things, a court can

preclude evidence when there is unfairness or unequal treatment in discovery. Indeed, there are numerous situations where courts have reasonably imposed the sanction of preclusion against a party who fails to comply with discovery obligations or who acts to prevent the timely and fair completion of discovery. See, e.g., Third Wave Tech., Inc. v. Stratagene Corp., 405 F. Supp. 2d 991 (W.D. Wis. 2005); Lomascolo v. Otto Oldsmobile-Cadillac, Inc., 253 F. Supp. 2d 354 (N.D.N.Y. 2003); Ware Commc'ns, Inc. v. Rodale Press, Inc., Civ. No. 95-5870, 2002 WL 89604 (E.D. Pa. Jan. 23, 2002).

3. The Federal Rules of Civil Procedure also provide means for protecting the integrity of federal actions. For example, when a party affirmatively withholds discovery from its opponent without substantial justification, Rule 37 provides sanctions -- such as precluding the party from using such evidence at trial -- unless the failure to disclose is harmless. See, e.g., Fed. R. Civ. P. 37(b)(2)(B) (providing that an appropriate sanction for failing to obey a discovery order is to "prohibit[] that party from introducing designated matters in evidence"). Similarly, Rule 16(f) permits a court to impose any sanctions "as are just" (including preclusion sanctions permitted under Rule 37(b)(2)) for failure to obey a scheduling or pre-trial order. See Fed. R. Civ. P. 16(f). However, those remedies are not exclusive and do not override the court's inherent power. As stated by the First Circuit: "[T]he adoption of a federal procedural rule does not implicitly abrogate a district court's inherent power to act merely because the rule touches upon the same subject matter." Atl. Pipe, 304 F.3d at 142.

4. Applying the above principles to this case, and pursuant to this Court's inherent power to manage and control the disposition of the cases on its docket, preclusion of FDA evidence is necessary to preserve the fairness in this matter. The FDA

is a most important witness in this matter and is certainly central to Dr. Selden's defense. Yet despite the unfettered access, cooperation and assistance that the FDA provided to the SEC for nearly three years prior to this lawsuit, the FDA has asserted essentially every means in its power to oppose Dr. Selden's attempt to access this information. The SEC itself has now affirmatively joined in the FDA's approach to limit the types of discovery that Dr. Selden may obtain from the FDA because they apparently do not comport with how the SEC wishes to try its case. Dr. Selden's access to FDA documents and witnesses has been substantially impeded and compromised by the FDA and now the SEC.

5. The actions of the government are clearly contrary to the spirit of open discovery embodied in Rule 26 and would never be tolerated by private litigants. However, in this case, the circumstances are even more problematical. Here, the plaintiff is the federal government, and the federal government (SEC in cooperation with FDA) has accused an individual citizen of committing securities fraud concerning the status of a biologics license application to the FDA. In attempting to restrict Dr. Selden's access to potentially exculpatory information, the government's conduct threatens Dr. Selden's rights to due process and access to the courts. See S.E.C. v. Rivlin, Civ. No. 99-1455, 1999 WL 1455758, *3 (D.D.C. Dec. 20, 1999) (recognizing that a defendant has "full due process rights" when "the SEC, pursuant to its investigation, either files a complaint or makes a criminal reference") (citation omitted). See also Westinghouse Elec. Corp. v. City of Burlington, 351 F.2d 762, 767 (D.C. Cir. 1965) ("[T]he paramount interest of the Government in having justice done between litigants in the Federal courts militates in favor of requiring a great effort on its part to produce any documents relevant to a fair termination of this litigation.").

6. For all of these reasons, this Court should enter an Order barring the SEC from introducing or relying on in dispositive motions or at trial any materials, testimony or other evidence derived or received from the FDA, any of its sub-agencies or departments, or any of its current or former employees.

Dated: October 27, 2006
Boston, Massachusetts

Respectfully submitted,

/s/ Thomas J. Dougherty

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**CERTIFICATE OF SERVICE**

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on October 27, 2006.

Dated: October 27, 2006

/s/ Justin J. Daniels
Justin J. Daniels